09/049,857

Filed

March 27, 1998

advancing a therapy catheter into said blood vessel until it reaches said occlusion; performing therapy on said occlusion;

utilizing fluid pressure within said vessel to inhibit particles produced during therapy from substantial migration in a direction proximal to said occlusion;

removing said therapy catheter;

creating a flow of fluid within said vessel in a proximal to distal direction by aspirating fluid from said working area inside the vessel at a location proximal to the occlusive device and distal to at least some of said particles whereby said particles are removed from the working area and said fluid pressure provides fluid to replace fluid aspirated from the working area; and

deactivating said occlusive device and removing said catheter.

- 16. The method of Claim 15, further comprising inserting a distal end of a debris removal device into said working area to a position just proximal to said occlusive device following the removal of said therapy catheter and aspirating fluid through said debris removal device.
- 17. The method of Claim 16, wherein said debris removal device comprises an aspiration catheter.
 - 18. The method of Claim 17, wherein said first catheter comprises a guidewire.
- 19. The method of Claim 17, wherein said aspiration catheter comprises a hollow lumen, and wherein said aspiration catheter is delivered by inserting a proximal end of said first catheter into said hollow lumen and slidably advancing said aspiration catheter over said first catheter.

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09/049,857

Filed

March 27, 1998

The method of Claim 17, wherein said aspiration catheter comprises a hollow lumen and a separate first catheter lumen, and wherein said aspiration catheter is delivered by inserting a proximal end of said first catheter into said first catheter lumen and slidably advancing said first catheter lumen over said first catheter.

- 21. The method of Claim 17, wherein said distal end of said aspiration catheter is inserted at least one time to a position no more than about 5 cm proximal to said occlusive device and thereafter slidably withdrawn in a proximal direction.
- 22. The method of Claim 15 wherein said blood vessel is selected from the group consisting of a saphenous vein graft, a coronary artery, and a vessel above the aortic arch.
- The method of Claim 15, wherein said blood vessel has a fluid flow rate of at least 23. about 10 cc per minute.
- The method of Claim 15, wherein said blood vessel has a fluid flow rate of from 24. about 60 to about 80 cc per minute.
- 25. The method of Claim 15, further comprising inserting a guide catheter to aid in the insertion of said occlusive device and said catheters.
- 26. The method of Claim 25, wherein said guide catheter is used for aspirating fluid from said working area.
- 27. The method of Claim 15, wherein activating said occlusive device results in the vessel being substantially occluded.
- The method of Claim 15, wherein said occlusive device is a balloon and said 28. activating step comprises inflating said balloon.

09/049,857

Filed

March 27, 1998

29. The method of Claim 15, wherein said occlusive device is a filter and said activating step comprises deploying said filter to prevent migration of particles downstream.

- 30. The method of Claim 15, wherein performing said therapy comprises delivering a drug directly to the site of said occlusion.
- 31. The method of Claim 15, wherein performing said therapy comprises creating a venturi effect within said vessel to aspirate said occlusion, and wherein the fluid aspiration occurs simultaneously.
- 32. The method of Claim 15, wherein performing said therapy comprises creating fluid turbulence within said vessel to aspirate said occlusion, and wherein the fluid aspiration occurs simultaneously.
- The method of Claim 15, wherein said therapy catheter is selected from the group 33. consisting of a thrombectomy catheter, a rheolitic device, and a device which creates a venturi effect within the vessel, and wherein the therapy and the fluid aspiration are performed simultaneously.
- The method of Claim 15, wherein the fluid aspiration is performed using said first 34. catheter.
- The method of Claim 15, wherein said therapy catheter is removed after the fluid is 35. aspirated.
- The method of Claim 15, wherein said flow of fluid is created across said occlusion 36. in a proximal to distal direction.
- The method of Claim 16, further comprising moving the distal end of the debris removal device within said working area during aspiration.

-4-

09/049.857

Filed

: March 27, 1998

The method of Claim 36, wherein the emboli are located in a segment of the blood vessel having substantially no side branches.

39. A method for the treatment of an occlusion in a blood vessel having a fluid pressure of at least about 0.2 psi, comprising:

inserting a catheter having an occlusive device at its distal end into said blood vessel, until said occlusive device is distal to said occlusion;

activating said occlusive device to at least partially occlude said vessel distal to said occlusion and create a working area surrounding said occlusion;

simultaneously delivering a therapy catheter and a debris removal device into said blood vessel until they reach said occlusion;

performing therapy on said occlusion;

utilizing fluid pressure within said vessel to inhibit particles produced during therapy from substantial migration in a direction proximal to said occlusion;

creating a flow of fluid within said vessel across said occlusion in a proximal to distal direction by aspirating fluid from said working area inside the vessel at a location proximal to the occlusive device, whereby said particles are removed from the working area and said fluid pressure provides fluid to replace fluid aspirated from the working area; and

removing said therapy catheter;

removing said debris removal device; and

deactivating said occlusive device and removing said catheter.

40. The method of Claim 39, wherein said blood vessel has a flow rate of at least about 10 cc per minute.



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09/049,857

Filed

March 27, 1998

- 41. The method of Claim 39, wherein said blood vessel has a fluid flow rate of from about 60 to about 80 cc per minute.
 - 42. The method of Claim 39, wherein said catheter comprises a guidewire.
- 43. The method of Claim 42, wherein at least a portion of said debris removal device or said therapy catheter is slidably advanced over said guidewire during said delivery.
- 44. The method of Claim 39, wherein said debris removal device comprises an aspiration catheter.
- 45. The method of Claim 39, wherein at least a portion of said debris removal device or said therapy catheter is slidably advanced over said catheter during said delivery.
- 46. The method of Claim 45, further comprising removing said therapy catheter prior to said aspirating.
- 47. The method of Claim 39, further comprising inserting said therapy catheter into a lumen of said debris removal device prior to said delivery.
- 48. The method of Claim 47, further comprising removing said therapy catheter prior to aspirating fluid.
- 49. A method for the removal of an occlusion in a blood vessel having a fluid pressure of at least about 0.2 psi, comprising:

inserting a catheter having an occlusive device at its distal end into said vessel, until said occlusive device is distal to said occlusion;

activating said occlusive device to at least partially occlude said vessel distal said occlusion and create a working area surrounding said occlusion;

09/049,857

Filed

March 27, 1998

allowing said fluid pressure within said vessel to prevent any particles dislodged during insertion of said catheter from flowing against said pressure and out of said working area;

inserting a distal end of a debris removal device to a position just proximal to said occlusive device;

aspirating fluid from said working area inside the vessel just proximal to the occlusive device to aspirate said occlusion and said particles while allowing said fluid pressure to provide irrigation fluid within said area;

removing said debris removal device; and

deactivating said occlusive device and removing said catheter.

The method of Claim 49, wherein said distal end of said debris removal device in inserted at least one time to a position no more than about 5 cm proximal said occlusive device.

51. A method for the treatment of an occlusion in a blood vessel having a fluid pressure of at least about 0.2 psi, comprising in the following order:

inserting a catheter having an occlusive device at its distal end into said blood vessel, until said occlusive device is distal to said occlusion;

activating said occlusive device to at least partially occlude said vessel distal said occlusion and create a working area surrounding said occlusion;

simultaneously delivering a therapy catheter and a debris removal device into said blood vessel until they reach said occlusion;

performing therapy on said occlusion;

09/049,857

Filed

March 27, 1998

utilizing fluid pressure within said vessel to inhibit particles produced during therapy from substantial migration in a direction proximal to said occlusion;

removing said therapy catheter;

creating a flow of fluid within said vessel across said occlusion in a proximal to distal direction by aspirating fluid from said working area inside the vessel at a location proximal to the occlusive device, whereby said particles are removed from the working area and fluid pressure provides fluid to replace fluid aspirated from the working area;

removing said debris removal device; and

deactivating said occlusive device and removing said catheter.

A method of treatment of a blood vessel in which blood flows proximally to

distally, said method comprising:

utilizing an expandable device to inhibit emboli suspended in said blood from migrating in a proximal to distal direction;

utilizing fluid pressure within said vessel to inhibit migration of said emboli in a distal to proximal direction;

advancing a catheter having a lumen in fluid communication with a distal opening in the catheter, said advancing comprising moving said distal opening relative to said expandable device within the blood vessel such that said opening is distal to at least a portion of an occlusive substance within said blood vessel, said occlusive substance comprising said emboli suspended in said blood;

drawing blood from the vessel into the distal opening such that (a) a blood flow is created in the lumen in a distal to proximal direction, and (b) said blood flow is

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09/049,857

Filed

March 27, 1998

simultaneously created in said vessel in a proximal to distal direction, whereby said emboli are carried by said blood flow from said vessel into said distal opening and through said lumen of said catheter.

53. The method of Claim 52, wherein the occlusive substance additionally comprises material on a wall of the vessel.

54. The method of Claim 52, wherein said advancing comprises moving said distal opening such that said opening is distal to at least some of the emboli.

55. The method of Claim 52, further comprising moving the distal opening in the catheter during said drawing of blood.

- 56. The method of Claim 52, wherein said expandable device is an occlusive device.
- 57. The method of Claim 52, further comprising advancing a guide catheter until a distal end of the guide catheter is positioned in the aorta, and wherein said catheter is advanced through said guide catheter.
- 58. The method of Claim 52, wherein said fluid pressure is provided by blood from the aorta.
- 59. The method of Claim 52, wherein said blood vessel comprises a saphenous vein graft.

REMARKS

New claims 15-59 are being carried over from the co-pending parent application, Serial No. 08/813,807, filed on March 6, 1997, and correspond to claims 1-32 and 43-55 of that application. New Claims 15-59 have all been <u>allowed</u> in the previous application.

34